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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/299,139	04/23/1999	JEFFREY BROWNING	A013	2882

7590 06/03/2005

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/299,139	BROWNING ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 51,53,55,56,59,71-73,75,77,78,84,86,88,89,95-98,100,102-104,106,108-112,114 and 116-121.

Continuation of Disposition of Claims: Claims rejected are 51,53,55,56,59,71-73,75,77,78,84,86,88,89,95-98,100,102-104,106,108-112,114 and 116-121.

DETAILED ACTION

Re: Browning *et al*

1. The amendment filed 2/24/2005 is acknowledged and entered into the record. Accordingly, claims 1-50,52,54,57-58,60-70,74,76,79-83,85,87,90-94,99,101,105,107,113, and 115 are canceled without prejudice or disclaimer, and claims 118-121 are newly added.

2. Upon further review and reconsideration, claims 95-98,100,102-104,106,108-112,114, and 116-117 will be rejoined and examined on the merits.

3. Claims 51,53,55-56,59,71-73,75,77-78,84,86,88-89, 95-98,100,102-104,106,108-112,114,116-117 and 118-121 are pending and examined on the merits.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

5. The disclosure is objected to because of the following informalities:

a. The drawings (i.e. figure 1) must be corrected to include a sequence identifier. MPEP 2422.02 indicates that *"when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings."*

Appropriate correction is required.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

6. The rejection of claims 53,59,75, 86, and now newly rejected claims 51,55-56,71-73,77-78,84,88-89,95-98,100,102-104,106,108-112,114, and 116-117 under 35 USC § 112§1st paragraph is maintained for the reasons of record. Applicant argues that the instant specification has provided sufficient support to identify the composition of the claimed agents. Specifically applicant argues that the soluble LTβR agent is to contain at least one ligand binding domain of LTβR. Applicant indicates that the specification teaches means of making the soluble LTβR and also indicates that any or all functional portions of the LTβR ligand binding domain are taught. Applicant additionally contends that the specification discloses working examples of how to synthesize LTβR soluble domains and means of using the soluble LTβR domains (i.e. examples 1-7). Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The specification of the instant application teaches generically that soluble LTβR domains are effective in mediating a humoral immune responses. Specifically, the specification teaches that LTβR of SEQ ID No: 1 (i.e. the extracellular domain of LTβR) is critical for this modulation. However, what the specification does not show is the breadth of the claimed invention. The specification does not show which portion of the soluble LTβR extracellular domain is critical for this function my means of a core structure or motif that is representative of the entire genus of soluble LTβR. The specification has only taught SEQ ID No: 1 and no other and therefore the single

species of SEQ ID No: 1 is insufficient to support the breadth of the genus encompassed by the claims. Moreover, since the disclosure fails to describe the common attributes or characteristics that identify members of the genus of "soluble LTβR", the disclosure of a single species is insufficient to teach the genus of soluble LTβR claimed.

Applicant additionally contends that given the state of the art and the teachings of the specification, one of skill in the art would readily recognize that applicant was in possession of the entire breadth of the genus claimed. Specifically, applicant argues that because SEQ ID No: 1 was present and taught in the specification, one of skill in the art could easily recognize Applicant's possession of all possible soluble forms of LTβR. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejections of record. Specifically, applicant is relying on the general knowledge and skill in the art to describe the omitted information concerning the soluble portions of LTβR, however, this is insufficient because it is specific not general guidance that is needed. Since the specification fails to describe the common attributes and or characteristics that identify the members of the genus, the disclosure of SEQ ID No: 1 alone is insufficient to describe the genus of soluble LTβR claimed.

Lastly, applicant contends that all possible species represented by a genus need not be disclosed if a representative number of species be disclosed. Applicant additionally contends that the disclosure of two working examples of soluble LTβR is sufficient to describe the scope of the instantly claimed invention. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome

the rejection of record. The working examples (i.e. example 1 and 2) teach the expression of human and murine soluble LTβR. Although these are two species of the LTβR, it does not support the breadth of all possible soluble LTβR, encompassed by the claims (i.e. fragments of LTβR, for example). The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3). Such is the case of the instantly claimed invention. The specification teaches SEQ ID No: 1 but claims any and all possible soluble LTβR ligand binding domains. No relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics have been disclosed.

In the absence of structural characteristics that are shared by members of the genus of "soluble LTβR comprising the ligand binding portion" or "functional fragment" of SEQ ID No: 1, the skilled artisan would conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in

possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Therefore, the rejection of claims under 35 USC 112, 1st paragraph is newly applied and maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 102

7. The rejection of claims 51,53,55-56,59,71-73,75,77-78,84,86,88-89 and now newly rejected claims 95-97,100,102-104,106,108-112,114, and 116-121 under 35 USC § 102 as being anticipated by Browning *et al* (US Patent 5,925,351, herein `351) is maintained for the reasons of record. Applicant argues that the claims of the instant invention are drawn to methods of treating "non Th1 cell mediated responses" as opposed to the invention of `351, which are drawn to methods of treating Th1 cell mediated immune responses. Applicant's main contention is that the claims of the instant invention are drawn to humoral responses, while the invention of `351 are solely drawn methods of treating cell mediated or Th1 type responses with a soluble LTβR. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or

intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). Such is the case of the instant invention. It appears that the product administered by Browning *et al* in the `351 patent is identical to that of the instant invention and therefore, the product would inherently perform the same function as that taught in the `351 patent. Therefore, the preamble of the claim is not considered a claim limitation and is of no significance to the claimed invention (i.e. the preamble only states a purpose or intended use of the claimed product).

Newly rejected claims are anticipated by Browning *et al* (US Patent 5,925,351) because Browning *et al* teach a method of administering of a soluble LTβR of SEQ ID No: 1. Browning *et al* also teach that the soluble LTβR can be fused to a heterologous domain such as an immunoglobulins, or more specifically a human Fc domain (see col. 4, for example). While Browning *et al.* do specifically characterize soluble LTβR fragments are used for the treatment of non-Th1 related diseases, the claimed functional limitation would be an inherent property of the soluble LTβR, because there does not appear to be a patentable distinction between the products of the claimed invention and that taught in the prior art. Moreover, it does not appear that the claim language or limitation results in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue

Laboratories 58 USPQ2d 1508 (CAFC 2001). Therefore, in the absence of evidence to the contrary, the burden is on the applicant to prove that the method of using the claimed soluble LTβR is different from that taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTOPHER YAEN
ART UNIT 1642
MAY 31, 2005

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
5/31/05